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PATENT  
Docket No.: 48317USA3C:014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Serial No.: 08/240,877

Filed: May 11, 1994

For: UNIDIRECTIONAL FLUID VALVE

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF BRIAN S. MCGINLEY

I, Brian S. McGinley, being duly sworn, state as follows:

1. I presently hold the position of Product Marketing Manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, St. Paul, Minnesota. In this position I am responsible for pricing, promotion, packaging, and positioning of 3M OH&ESD respiratory products.

2. I have been working in the respiratory field for the past 18 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use exhalation valves to purge warm, moist exhaled air from the mask interior.

3. I am familiar with the subject matter of the above-captioned patent application, and I have reviewed the claims pending in this application and understand their scope and content.

4. I have witnessed the evolution of the art in respiratory products, in particular the evolution of the exhalation valve art on filtering face masks. On information and belief, I believe that the following sequence of events has occurred in this field:

a. Before May 29, 1992, 3M invented a filtering face mask that comprised a mask body and an exhalation valve. The mask body was adapted to fit over the nose and mouth of a person and had a filtering layer for filtering air that passed through the mask body.

**EVIDIT E**

The exhalation valve was attached to the mask body, and it comprised a valve seat that included an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also had a single flexible flap that had a stationary portion, one free portion, and a circumferential edge that included stationary and free segments. The stationary segment of the circumferential edge was associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation, and the free segment of the circumferential edge was associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge was disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

This filtering face mask differed from known commercial products in that the flexible flap was noncentrally secured to the valve seat (relative to the orifice) at the flap retaining surface, and the flap retaining surface and seal surface were nonaligned and positioned relative to each other to allow for a cross-sectional curvature of the one free portion of the flexible flap when viewed from the side in a closed position. The nonalignment and relative positioning of the flap-retaining surface and the seal surface also allowed for the free portion of the flexible flap to be pressed towards the seal surface when a fluid was not passing through the orifice and to allow for the free portion of the flexible flap to be lifted from the seal surface during an exhalation.

b. On December 9, 1993, the filtering face mask described in paragraph 4.a was first published in International Publication WO 93/24181. This new filtering face mask was also published in U.S. Patent 5,325,892 on July 5, 1994.

c. In 1993, OH&ESD introduced in Europe its filtering face mask product that had a valve that included the structure described above in paragraph 4a. An Example of this kind of valve is attached to this Affidavit as Exhibit A. This product meets all of the limitations of the broadest claim pending in the above-captioned application (claim 78).

d. Before 3M's publication and introduction of the new filtering face mask product referred to in paragraphs 4.a and 4.b, it is my understanding and recollection, that essentially all previous commercial filtering face mask products had used an exhalation valve that had a centrally-mounted flap. Known valves that had centrally-mounted flaps

mainly had a circular flap member that was mounted to a valve seat through a central stake or button. These valves are commonly referred to in the art as "button-style" valves and had been used on 3M commercial filtering face masks for approximately 13 years before 3M's original filing date of the flapper-style valve of claim 78. Examples of button-style valves are shown in U.K. Patent Application 2,072,516A (Fig. 3) published 1981, U.S. Patent 2,895,472 (Fig. 5) published 1956, U.S. Patent 2,230,770 (Figs. 11-14, 27-29) published 1940, and U.S. Patent 4,630,604 (Figs. 1, 2 and 4-5) published 1986. Another centrally mounted valve — although not nearly as common — had been (and continues to be) sold by OH&ESD in Europe and is described in U.S. Patent 4,934,362 to Braun. This latter product is not referred to as a button-style valve. But the flap is centrally-mounted to the valve seat by a central bridge.

e. In 1995, Racal Health & Safety introduced in the United States a filtering mask that had a flapper-style valve. This new Racal mask had an exhalation valve that was similar to the structure and function of the flapper valve product that was previously published and introduced by OH&ESD and claimed in the above-caption application. A sample of this product is attached to this Affidavit as Exhibit B. This valve is also shown and described in Racal's U.S. Patent No. 5,687,767. Like the invention claimed in the present application, the Racal product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

f. Around approximately late 1998, Moldex Metric Inc. introduced in the United States a filtering face mask that also had a flapper-style valve. This new Moldex mask had an exhalation valve that was similar to the structure and function of the flapper valve

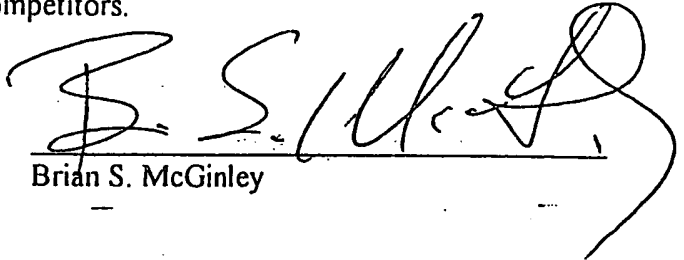
product that was previously published and introduced by OH&ESD and claimed in the above-captioned application. Moldex Metric sells this valve under the trademark Ventex™. A sample of this product is attached to this Affidavit as Exhibit C. This valve is also described in Moldex's U.S. Patent No. 6,047,698, filed August 20, 1998. Like the invention claimed in the present application, the Moldex product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

g. In approximately 1999, Ever Green Co. Ltd. of Korea introduced a filtration face mask product in that country, which mask was similar in structure and function to the respiratory product previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of their product is attached to this Affidavit as Exhibit D. Like the invention claimed in the present application, the Korean product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

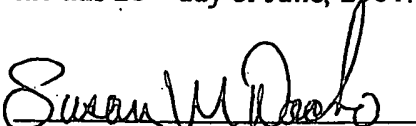
h. In approximately March of 2000, Louis M. Gerson -Company introduced in the United States a filtering face mask product that was similar in structure and function to the filtering face mask previously published and introduced by OH&ESD and claimed in the above-captioned application in paragraphs 4. a-c above). An example of this product is attached to this Affidavit as Exhibit E. Like the invention claimed in the present application, the Gerson product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

i. In approximately November of 2000, Survivair (division of Bacou USA Safety Inc.) introduced a filtering face mask product that had an exhalation valve similar in structure and function to the exhalation valve previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of this product is attached to this Affidavit as Exhibit F. Like the invention claimed in the present application, the Survivair product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

5. The public disclosure and introduction of the OH&ESD filtration face mask product of the above-captioned invention — followed closely by five competitive products that share the same new technology previously disclosed and claimed in the above-captioned application, and coupled with the fact that no previous filtering face mask product used this technology but primarily relied on centrally-mounted flap valve technology, particularly button-style valves — lead me to the firm conclusion that the technology first created by OH&ESD and claimed in the present application was copied by each of these competitors.

  
Brian S. McGinley

Subscribed and sworn to before  
me this 28<sup>th</sup> day of June, 2001.

  
Notary Public

